

REMARKS

Claim 19 is amended by inserting the features of claims 25 and 26, and by reciting that the excipient of the inner core consists of, rather than comprises, two components. The present amendments were made to expedite prosecution, and applicants reserve the right to pursue any cancelled subject matter in this or in a continuing application. No new matter has been added.

Claims 25, 26, and 29 are canceled.

Specification

The disclosure is objected due to an informality on page 26, line 25. Applicants respectfully submit that the above-specified amendment to the specification overcome such objection ground.

Claim Objections

Claim 29 is objected as being a duplicate of claim 27. Applicants respectfully submit that the above-specified amendment to the claims renders this objection moot.

Claim Rejections – 35 U.S.C. § 112

Claim 30 is rejected by the Examiner because the list of chemical species for the plasticizer is unclear. Applicants respectfully submit that, by using a comma before and after each item, only the first interpretation given by the Examiner was intended, i.e. an

ester of a fatty acid with propylene glycol, and esters formed between glycerol and sugars, were not intended. Under these circumstances, Applicants respectfully submit that claim 30 is clear and requires no amendment.

Claim Rejections – 35 U.S.C. § 102

Claims 19, 23, 24, 27, 29 and 31 are rejected under 35 U.S.C. § 102(b) as anticipated by Bar-Shalom (WO 95/22962).

Claim 19 has been amended to include the limitations of claims 25 and 26, which are free of the section 102 rejection. Accordingly, in view of this amendment, the section 102 rejection should be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 19, 20, and 23-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Shalom (WO 95/22962).

Applicants respectfully submit that claim 19, as amended, is free of the present ground of rejection in view of Bar-Shalom.

It is clear from the teaching of Bar-Shalom, for example, at page 5, lines 19-25, that the matrix of the inner core includes a crystalline polyethylene glycol polymer in which at least one non-ionic emulsifier is dispersed. In order for the emulsifier to be dispersible into the crystalline polyethylene glycol polymer, the emulsifier has at least one domain which is compatible with the crystalline polyethylene glycol polymer (see, for

example, page 23, lines 22-28, claim 18). This is why a preferred non-ionic emulsifier for use in the matrix is polyethylene glycol stearate (page 5, lines 25-27). No other embodiment of the matrix is described in Bar-Shalom.

The excipient of the inner core does not include a crystalline polyethylene glycol polymer, since it consists of a hydrophilic cellulose polymer and an amphiphilic material. Due to this difference, there is no need for the amphiphilic material of amended claim 19 to be restrictively selected to be dispersible into a crystalline polyethylene glycol polymer.

Moreover, the only embodiment of Bar-Shalom where a cellulose derivative is present in the inner core is Example 2 quoted by the Examiner. In this embodiment, the amount of cellulose derivative is 3% by weight of the inner core (matrix), i.e. much lower than the minimal amount of the hydrophilic cellulose polymer required in amended claim 19. In this embodiment of Bar-Shalom, starch is also present as the major component

Thus, starting from the teaching of Bar-Shalom to arrive at the presently claimed invention, one skilled in the art needs not merely to replace one component with a functional equivalent as suggested by the Examiner. Rather, the skilled person needs to realize that:

- the crystalline polyethylene glycol polymer may be removed, and
- as a consequence of this component removal, the definitions and amounts of the other excipients of the inner core need to be significantly modified.

Applicants respectfully submit that the above-specified modifications of Bar-Shalom go far beyond the ordinary skill and cannot be designed without making an inventive contribution. These modifications constitute a significant simplification of the drug delivery compositions of Bar-Shalom, the success of which could not be reasonably expected at the time the invention was made.

Claims 19 and 21-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Shalom (WO 95/22962) in view of Santus et al. (U.S. Patent 5,503,843; “Santus”).

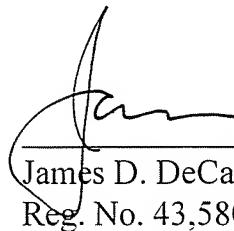
Applicants respectfully submit that claim 19, as amended, is free of the present rejection.

As indicated by the Examiner, the complementary teaching from Santus is about plasticizers. However, as is explained above, the claimed compositions, with respect to Bar-Shalom, are unrelated to the plasticizer. Santus fails to remedy the deficiencies of Bar-Shalom and, accordingly, fails to enable the skilled person to envisage any of the modifications of Bar-Shalom which are necessary to arrive at the presently claimed invention.

Conclusion

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,



James D. DeCamp
Reg. No. 43,580

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045